Section A: General Information

Summary and Report

Description	Date(s)
Internal Audit Main Event (1-2 weeks)	April 13, 2018 through June 11, 2018
Internal Audit Main Event Closing Meeting	Scheduled to coincide with the monthly and/or annual management review (AMR) in October 2018
Report Submit to CRL Directors	06/18/17 (mid-year) and again upon completion

Note: The *Internal Audit Main Event Closing Meeting* does not apply to this QSA since the CRL QA Coordinator (with some assistance) performed the entire audit. Management is notified of all audit findings through the monthly QA-Management monthly meetings. CRL staff members are notified with a summary of the audit during the monthly QA lab-wide meeting. Individuals (observed analysts) participating in the audit are notified of any findings as they were discovered.

Title	Audit Function	Name	Position	Experience
Lead Assessor	ISO 17025, Section 4, Reviews, Reports	Angela Ockrassa Davis	QA Coordinator	Internal system and SOP audits
Assessor 1	ISO 17025: 2002 Section 5	Angela Ockrassa Davis	QA Coordinator	Same as above
Assessor 2	ILAC G19: 2002 Forensic Science	Angela Ockrassa Davis	QA Coordinator	Same as above
Assessor 3	SOP Activity Witnessing SOP activity	Angela Ockrassa Davis Amanda Wroble Robert Thompson	QA Coordinator QA group member (Inorg.) QA group (Org.)	Same as above *Overseen by QAC *Overseen by QAC

Note: All assisting assessor are overseen by the Lead assessor.

Section B: Findings Summary

	Audit Description	Y/N	[1]Finding(s)	[2]Workflow ID(s)
1	Were previous year CA(s) implementation and/or effectiveness confirmed?	Y/N	Concern 01 & 02	See section C
2	Was CRL checklist 004-A, Internal system audit for ISO 17025 components, completed?	Y	3 N/C 1 concern	See section C
3	Was CRL checklist 004-B, Internal system audit for ILAC G-19 (CIS) components, completed?	Y	0	Doc #14465
4	Was CRL checklist 004-C, Internal SOP activity audit(s) for witnessing, completed?	Y	multiple	See page 3
5	Follow up audit recommended/scheduled?	N	n/a	See page 3
6	Concerns/comments/recommendations provided?	Y	various	See page 3
7	Deficiency findings identified?	Y	See page 3	See page 3

[1] State the number of finding(s) base on deficiencies unless otherwise specified.

[2] Qualtrax workflow IDs: CAR or Task (Request)

*Note: SOP audits (witnessing and technical data reviews) are completed throughout the calendar year so their associated findings are to be determined (TBD). This report is generated mid-year (for ISO 17025, Forensics, and general internal system audit).

Acronyms and Definitions

Comment: A finding about documents or practices with a potential of improvement; but still fulfilling the requirements. Any comments found during this audit are summarized at the end of this report.
Concern: A finding where, in the opinion of the audit team, the practice may develop into a noncompliance or nonconformity. Any concerns discovered during this audit are summarized following this section.

Finding: An audit conclusion referenced to a requirement and supported by objective evidence that identifies compliance with and/or a deviation from the requirement. NOTE: Lack of evidence identifying compliance with a requirement is a finding.

Non-compliance: A finding where the documents or practices do not meet the requirements of the ISO 17025 standards, the SOPs, the QMP, or other regulatory programs in a way that jeopardizes the quality of work. Any non-compliances discovered during this audit are summarized following this section.
Non-conformance: A finding that lacks in characteristic, documentation or procedure rendering the quality of the item or activity unacceptable. A technical finding can be a type of non-conformance. Any non-conformances discovered during this audit are summarized following sections.

Section C: Finding Descriptions

ISO and general internal QSA findings**:**

-- Concerns –

ISO Concern 01: 2017 Internal QSA review and follow-up – The retention record for purchase cards was identified as a non-compliance during the 2017 internal QSA and the revised SOP GEN018 version does not address it. This is concern that was identified by the QSA which is why the associated CAR 10972 has not yet been closed.

-- Non-Compliances –

ISO Non-compliance 01: ISO section 4.3.1 Checked and verified as a non-compliance 01 on 05/30/18. Section 4.3.1 requires a master list to identify and locate records, but some of the record locations stated in the associated master list work instruction are either incorrect or missing. CRL' master list procedure via Qualtrax (master list report) documented in QA-WI003 does not contain all of the internal records as claimed in the associated work instruction. I.e. QA lab-wide or group meeting minutes. Also, QMP section 11.1 states that for records and details refer to G:\CIT – CRL Improvement Team, but they are not available in the OneDrive CIT Notebook instead. See CAR # 14653.

ISO Non-compliance 02: ISO section 4.13.2.3 was checked on 06/08/18 and discovered to be non-compliant in various account of data verification. Section 4.13.2.3 requires mistakes to be single-line

crossed out, correct entry made, and signed or initialed by person making correction. This was not the observed practice. See CAR 14558 & 13955, 13234.

ISO Non-compliance 03: ISO section 5.4.1 states that deviation from test methods must be approved by management and the client and provide a technical justification. A deviation in from the CWA for DOC was discovered as non-compliant to the stated standard section in some CRL organic SOPs. The CWA methods have limits (X_bar) for DOCs that are different and tighter than the LCS limits currently used in some CRL SOPs which are used for DOC acceptance criteria. DOC X bar limits are tighter than the LCS MS/MSD limits (e.g. table 6 from 625.1, table 7 from 624.1). Therefore, since some CRL SOPs (i.e. SOPs with method reference 608,624,625) are using LCS MS MSD limits which are not specifically listed in part 136.6 (allowable method modifications) for use in determining a passing DOC, the associated CRL SOPs are deviating from the method references.
See CA #14779.

SOP Audit findings**:**
For a description of all findings, refer to the audit report/checklist associated with the SOP witnessed. To review the SOP audit schedule and detailed assessment information, including the data provided directly below, refer to document #5467. All deficiency findings are reviewed by QA Coordinator and the deputy director. When needed, both parties plus the laboratory director discuss them during QA-management monthly meetings.

Technology	Date Started	Auditor	SOP	Analyst	WO #	CA # (findings)	Date Completed	Audit Rpt ID#	Comments
Electrometric	16-Jan-18	AO	AIG002	CB	1710021	14085 (1)	15-May-18	14106	no samples in-house
Gravemetric	24-Feb-18	AO	AIG017	NF	1707020	none	12-Jun-18	14110	no samples in-house
Electrometric	21-Feb-18	AO	AIG003	CB	1705002	14085 (2)	15-May-18	14106	no samples in-house
GC	22-Feb-18	AO	GC001	ES	1709001	13955 (2) 14545 (1)	8-Jun-18	14108	no samples in-house
Electrometric	21-Mar-18	AO	AIG004A	CB	1704004	none	11-Jun-18	14109	no samples in-house
GC	4-Mar-18	AW	GC003	DL	1712005	14558 (4)	4-Jun-18	14554	no samples in-house
Electrometric	10-Apr-18	AO	AIG015A v3	CB	171210	none so far	pending data review	13919	no samples in-house
MS	12-Apr-18	AO	MS001	MK	1710015	1 concern so far	pending data review	14112	no samples in-house
ICP-MS	30-May-18	AO	Metals001	AW	1805011	none so far	pending data review		--
MS	3-May-18	AO/AW	MS005	WW	1804008 (PT)	1 concern so far	pending data review		--
OM	6-Jun-18	AO	OM021	LZ	1805016	14783 (1) so far	pending data review		--